A Randomized Clinical Trial of Jet-Injected Lidocaine to Reduce Venipuncture Pain for Young Children

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Study objective: The J-Tip (National Medical Products Inc, Irvine, CA) uses air instead of a needle to push lidocaine into the skin. To our knowledge, no studies have investigated its use for venipuncture in young children. We determine whether the J-Tip decreased venipuncture pain in young children compared with vapocoolant spray.

Methods: Children aged 1 to 6 years were randomized into 3 groups: intervention (J-Tip), control (vapocoolant spray), and sham (vapocoolant spray and pop of an empty J-Tip). The procedure was videotaped and scored with the Face, Legs, Activity, Cry and Consolability (FLACC) tool at 3 points; baseline, before approach; device, at J-Tip deployment; and at venipuncture. The FLACC tool was scored 0 (none) to 10 (severe). Comparisons of pain scores over time were made with the generalized estimating equation. Venipuncture success and adverse effects were assessed and compared with χ^2.

Results: Two hundred five children enrolled: intervention 96, control 53, and sham 56. There were no between-group differences in baseline characteristics. There was no mean change in pain scores from device to venipuncture in the intervention group (0.26; 95% confidence interval [CI] −0.31 to 0.82), but there was an increase in pain in the control (2.82; 95% CI 1.91 to 3.74) and sham (1.68; 95% CI 0.83 to 2.52) groups. This change was greater for the control and sham compared to the intervention group. There was no difference in venipuncture success between groups. No severe adverse events occurred. Minor adverse events were the same between groups.

Conclusion: Use of the J-Tip for children aged 1 to 6 years reduced venipuncture pain compared with vapocoolant spray or sham treatment. [Ann Emerg Med. 2015;66:466-474.]

Please see page 467 for the Editor's Capsule Summary of this article.

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INTRODUCTION

Background

Needle sticks are a common source of pain for pediatric patients. Untreated pain has been correlated with strong negative responses and greater pain with subsequent needle sticks.[1,2] Additionally, painful medical experiences during childhood are associated with increased adult pain sensitivity and failure to seek health care.[1] Efforts to improve pain treatment for children are needed to reduce these unwanted effects.

Venipuncture can cause moderate to severe pain, especially in young children. A study of children aged 3 to 17 years found that 36% of those aged 3 to 6 years and 13% of those aged 7 to 17 years experienced moderate to severe levels of pain during venipuncture. Because the youngest children report more pain, they may benefit the most from interventions to improve their pain experience.[3] The American Academy of Pediatrics advises minimizing pain during pediatric procedures including venipuncture.[4] Evidence-based interventions are needed to reduce the pain experienced by the youngest children during venipuncture.

The needle-free jet injection system with buffered lidocaine (J-Tip) (National Medical Products Inc, Irvine, CA) uses air instead of a needle to push lidocaine in to the skin (Figure 1), which provides local anesthetic at the site of administration in less than a minute, making it ideal for prevenipuncture anesthetic. Previous randomized clinical trials in children aged 8 to 15 years and 7 to 19 years found that the J-Tip was more effective than lidocaine or prilocaine cream for the treatment of pain during venipuncture for intravenous line placement.[5,6] Use of the J-Tip device itself was also not painful or associated with adverse events for children.[6] A randomized clinical trial in children aged 5 to 18 years undergoing intravenous line insertion or venipuncture for blood draw found that the

Editor's Capsule Summary

What is already known on this topic

The needle-free jet injection system with buffered lidocaine (J-Tip) reduces pain associated with intravenous line placement in older children and adolescents.

What question this study addressed

Does the J-Tip reduce venipuncture pain in younger children?

What this study adds to our knowledge

In this trial of 205 children aged 1 to 6 years, the J-Tip reduced venipuncture pain compared with either vapocoolant spray or sham. Procedural success rates and adverse events were similar across groups.

How this is relevant to clinical practice

Clinicians should consider use of a J-Tip to reduce venipuncture pain in young children.

device treated pain more effectively than no treatment, but found no difference in reported pain if the device injected lidocaine or normal saline solution.[7] These studies were conducted in the emergency department (ED) or preoperative settings.

Importance

To our knowledge, there is no published research evaluating the efficacy and safety of the J-Tip in children younger than 5 years, and there are only limited data for children aged 5 to 6 years.

Goals of This Investigation

The objective of this study was to determine whether the J-Tip decreased venipuncture pain in children aged 1 to 6 years. We hypothesized that the J-Tip would decrease venipuncture pain in young children compared with vapocoolant spray.

Figure 1. Photo of J-Tip device. Used with permission from National Medical Products, Inc.

MATERIALS AND METHODS

Study Design and Setting

This was a randomized single-dose clinical trial comparing the efficacy of the J-Tip device to vapocoolant spray for the reduction of venipuncture pain in young children. The children's pain experience was videotaped and later scored by physicians blinded to the group assignment. The study received institutional review board approval and was registered with clinicaltrials.gov (NCT01890642). Verbal and written consent was obtained from all parents. This study was conducted from July 1, 2013, to August 8, 2013, in the outpatient laboratory at a tertiary care children's hospital. A convenience sample of eligible patients was approached for enrollment when the research team was available Monday through Friday between 9 AM and 5 PM.

Selection of Participants

Children aged 1 to 6 years with orders for a blood draw were eligible for the study. Patients were excluded if they were allergic to lidocaine or vapocoolant spray, had a blood or connective tissue disorder that predisposed them to bruising, experienced a previous blood draw the same day, were not having blood draw by venipuncture (children with a central line for blood draws or with finger-stick blood draws), were not accompanied by a parent or legal guardian, had parents or legal guardians who were non-English speaking, or were unable to cry or move their extremities.

After eligibility criteria were confirmed, data on personal characteristics and previous venipuncture experience were gathered from parent report. A random-number table was used to assign children at a 2:1:1 ratio to intervention, control, and sham groups. Uneven group numbers were used to give patients a 50% chance of receiving the intervention and a 50% chance of being in the control or sham group. Study group assignment was not revealed to the research team before completion of the consent process.

Interventions

The intervention group received 0.2 mL of 1% buffered lidocaine administered with a J-Tip followed by a spray of normal saline solution before venipuncture. Children in the control group received only vapocoolant spray at the site just before venipuncture. Vapocoolant is usual care at this institution. The sham group had an empty J-Tip deployed near the venipuncture site to create the loud pop and also